

Terrestrial Animal Health Standards Commission Report September 2016

DRAFT CHAPTER 4.X.(N)

VACCINATION

Article 4.X.1.

Introduction and objectives

In general, *vaccination* is intended to control and prevent the occurrence of a *disease* and reduce the transmission of the pathogenic agent. For the purpose of *disease* control, vaccines should induce immunity that, ideally, prevents *infection*. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent. *Vaccination* may contribute to improvement of *animal* and human health, *animal welfare*, agricultural sustainability and to reduction of the use of *antimicrobial agents* in *animals*.

The *vaccination* strategy applied depends on technical and policy considerations, available resources and the feasibility of implementation. The recommendations in this chapter are intended for all *diseases* for which a vaccine exists.

In addition to other *disease* control measures, *vaccination* may be a component of a *disease* control programme. The prerequisites to enable a Member Country to successfully implement *vaccination* include compliance with:

- 1) the recommendations on *surveillance* in Chapter 1.4.;
- 2) the relevant provisions in Chapters 3.1. and 3.4.;
- 3) the recommendations on *vaccination* in the *disease*-specific chapters;
- 4) the principles of veterinary vaccine production in Chapter 1.1.8. of the *Terrestrial Manual*.

The objective of this chapter is to provide guidance to Member Countries for successful implementation of *vaccination* in support of *disease* control programmes. The recommendations in this chapter may be refined by the specific approaches described in the *disease*-specific chapters of the *Terrestrial Code*.

Standards for vaccines are described in the *Terrestrial Manual*.

Article 4.X.2.

Definitions

For the purpose of this chapter:

Vaccination programme: means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of *disease* control.

Emergency vaccination: means a *vaccination* programme applied in immediate response to an *outbreak* or increased *risk* of introduction or emergence of a *disease*.

Systematic vaccination: means an ongoing routine *vaccination* programme.

Vaccination coverage: means the proportion of the target population to which vaccine was administered during a specified timeframe.

Population immunity: means the proportion of the target population effectively immunised at a specific time.

Article 4.X.3.

Vaccination programmes

The objectives of a *vaccination* programme should be defined by the *Veterinary Authority* before the implementation of the *vaccination* taking into account the epidemiology of the *disease*, the species affected and their distribution. If these factors indicate that the programme should be expanded beyond national boundaries, the *Veterinary Authority* should liaise with the *Veterinary Authorities* of neighbouring countries.

When appropriate, a regional approach to harmonise *vaccination* programmes is recommended.

Vaccination programmes may include systematic *vaccination* and emergency *vaccination*.

- 1) Systematic *vaccination* in infected countries aims to reduce the incidence of a *disease* with the objective of control and possible eradication. In *disease* free countries or *zones*, the objective of systematic *vaccination* is to limit the impact in the case of an introduction of *disease*.
- 2) Emergency *vaccination* provides an adjunct to the application of other essential *biosecurity* and *disease* control measures and may be applied to control *outbreaks*. Emergency *vaccination* may be used in response to:
 - a) an *outbreak* in a free country or *zone*;
 - b) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when vaccines are applied to boost existing immunity;
 - c) an outbreak in a country or *zone* that applies systematic *vaccination*, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the *outbreak*;
 - d) a change in the *risk* of introduction or emergence of *disease* in a free country or *zone*.

Vaccination programmes should consider other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing resources.

Article 4.X.4.

Launching a vaccination programme

When deciding whether to initiate a *vaccination* programme the *Veterinary Authority* should consider the following:

- 1) the probability that the *disease* cannot be rapidly contained;
- 2) an increased *incidence* of an existing *disease*;
- 3) an increased likelihood of introduction or emergence of a *disease*;
- 4) the density of susceptible animals;
- 5) an insufficient level of population immunity;
- 6) the *risk* of exposure of specific *subpopulations* of susceptible animals;
- 7) the suitability of *vaccination* as an alternative to or an adjunct to other *disease* control measures such as a *stamping-out policy*;
- 8) the availability of resources;
- 9) cost-benefit considerations of *vaccination*, including the impact on trade.

Article 4.X.5.

Vaccination strategies

Different *vaccination* strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the *disease*. The following strategies may be applied:

- 1) **Blanket vaccination:** *vaccination* of all susceptible animals in an area or an entire country or zone.
- 2) **Ring vaccination:** *vaccination* primarily of all susceptible animals in a delineated area surrounding the *establishments* where an *outbreak* has occurred. To prevent outward spread of *disease*, *vaccination* should be applied from the outer boundary of the area inwards.
- 3) **Barrier vaccination:** *vaccination* in an area along the border of an infected country or zone to prevent the spread of *disease* into or from a neighbouring country or zone.
- 4) **Targeted vaccination:** *vaccination* of a *subpopulation* of susceptible animals defined by a greater likelihood of exposure or severity of the consequences.

Article 4.X.6.

Critical elements of a vaccination programme

In addition to the choice of vaccine, the *vaccination* programme should include the following critical elements and be communicated to all stakeholders.

1. Target population

The *vaccination* programme should define the animal population to be vaccinated and the geographical area where the target population is located.

The target population may include the entire susceptible population or an epidemiological relevant *subpopulation* depending on the likelihood of exposure, the consequences of the *disease*, the role of the different *subpopulations* in the epidemiology of the *disease* and the resources available. The target population may include *wildlife*.

Factors to consider in determining the target population may include species, age, maternal immunity, sex, production types, geographical distribution as well as the number of *animals* and *herds*. These factors should be reviewed and updated regularly.

2. Vaccination coverage

In practical terms, it may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary for the minimum population immunity required to achieve the objectives of the programme. The minimum population immunity required will vary according to the epidemiology of the *disease*, density of susceptible animals and geographical factors.

Measuring population immunity during the monitoring of the *vaccination* programme may assist to identify subsets of the target population that have not been adequately immunised.

3. Stakeholder involvement

The *vaccination* programme should demonstrate good governance by the *Veterinary Services* and clearly identify the involvement of different stakeholders including other government agencies, farmers, farmer organisations, private sector veterinarians, non-governmental organisations, *veterinary paraprofessionals*, local government authorities and vaccine suppliers. Stakeholder acceptance of *vaccination* is crucial for the success of the *vaccination* programme. Different stakeholders should preferably be involved in the planning and implementation of *vaccination*, the awareness campaigns, the monitoring of *vaccination*, the production and delivery of vaccines and the financing of the *vaccination* programme.

4. Resources

Vaccination programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the *vaccination* programme.

5. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

6. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of the *vaccination* campaigns. Depending on the *disease* and type of vaccine, animals may be vaccinated once or several times during their lifetime.

The objective of the *vaccination* campaign is to achieve the necessary *vaccination* coverage and the minimum population immunity in the target population within a defined timeframe. The *vaccination* campaign should be implemented in such a manner as to ensure that the majority of the target population is immunised within as short a time as possible. The *vaccination* programme should include a detailed description of the implementation of the *vaccination* campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of the *vaccination* campaigns should be determined taking into consideration the following factors:

- a) vaccine characteristics and manufacturer's directions for use;
- b) accessibility of the target population;
- c) animal handling facilities;
- d) animal body condition and physiological state;
- e) geographical factors;
- f) climate conditions;
- g) awareness, acceptance and engagement of stakeholders;
- h) types of production systems and animal movement patterns;
- i) timing of agricultural, social or cultural activities;
- j) availability of resources.

7. Auditing of the vaccination campaigns

The *vaccination* programme should include periodic auditing of the *vaccination* campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to the *vaccination* campaign include:

- a) proportion of *animals* and *herds* vaccinated within the defined timeframe;
- b) number of vaccine doses used compared with number of animals vaccinated;
- c) number of reports of breaches of the cold chain;
- d) performance of vaccinator teams in respect of the standard operating procedures;
- e) timing and length of the campaign;
- f) overall cost and cost per individual animal vaccinated.

To enable auditing of the *vaccination* programme, a recording system should be in place to measure the indicators above.

Article 4.X.7.

Choice of vaccine

Depending on the *disease*, several vaccines may be available. To achieve the objectives of the *vaccination* programme, the choice of a vaccine depends on different factors including:

1. Availability and cost

- a) availability of the vaccine in adequate quantities at the time required;
- b) capacity of the providers to supply the vaccine for the duration of the *vaccination* campaign and to respond to increased needs;
- c) flexibility in the number of doses per vial to match the structure of the target population;
- d) a comparison of the costs of vaccines that meet the technical specifications established in the *vaccination* programme.

2. Vaccine characteristics

- a) Physical characteristics
 - route and ease of administration;
 - volume of dose;
 - type of adjuvant and other components.
- b) Biological characteristics
 - immunity against circulating strains;
 - live, inactivated or biotechnology-derived vaccines;
 - number of strains and pathogens included in the vaccine;
 - potency of the vaccine;
 - onset of immunity;
 - shelf-life and expiry date;
 - thermostability;
 - duration of the effective immunity;
 - number of doses required to achieve effective immunity;
 - effect on the ability to differentiate infected from vaccinated animals, at the individual or group level;
 - suitability of vaccine formulation for species in the target population;
 - safety for the environment.
- c) Side effects
 - adverse reactions;
 - transmission of live vaccine strains.

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should be subjected to the registration procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Products (VICH).

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

National *disease* contingency plans should provide for emergency *vaccination*. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If *vaccination* is to be used systematically, definitive registration should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

2. Implementation of the vaccination programme

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables as well as standard operating procedures to:

- a) implement the communication plan;
- b) establish, maintain and monitor the fixed and mobile components of the cold chain;
- c) store, transport and administer the vaccine;
- d) clean and disinfect equipment and *vehicles*, including heat sterilisation of reusable equipment;
- e) dispose of waste;
- f) identify vaccinated animals;
- g) ensure safety and welfare of animals and *vaccination* teams;
- h) record activities of *vaccination* teams;
- i) document *vaccinations*.

The availability of appropriate animal handling facilities at the *vaccination* site is essential to ensure effective *vaccination* as well as safety and welfare of *animals* and *vaccination* teams.

3. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the *Veterinary Authority*. The *vaccination* programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of *vaccination* teams should be sufficient to implement the *vaccination* campaign within the defined timeframe. The *vaccination* teams should be adequately equipped and have means of transport to reach *vaccination* sites.

4. Public awareness and communication

The *Veterinary Authority* should develop a communication strategy in accordance with Chapter 3.3., which should be directed at all stakeholders and public to ensure awareness and acceptability of the *vaccination* programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the *vaccination*, target population and other technical aspects that may be relevant for the public to know.

5. Animal identification

Animal identification allows for the differentiation of vaccinated from non-vaccinated animals and is required for the monitoring and certification of *vaccination*.

Identification can range from temporary to permanent identifiers and can be individual or group-based. *Animal identification* should be carried out in accordance with Chapters 4.1. and 4.2.

6. Record keeping and vaccination certificates

Vaccination programmes under the *Veterinary Authority's* responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the *Veterinary Services* should consider issuing official certificates of the *vaccination* status of animals or groups of animals.

7. Additional animal health related activities

In addition to *vaccination* against a specific pathogenic agent, *vaccination* programmes may include other animal health-related activities such as *vaccination* against other pathogenic agents, treatments, *surveillance*, *animal identification* and communication.

Including additional animal health-related activities may enhance the acceptability of the *vaccination* programme. These activities should not negatively affect the primary objective of the *vaccination* programme.

Simultaneous *vaccination* against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.

Article 4.X.9.

Evaluation and monitoring of a vaccination programme

The *vaccination* programme should provide for outcome-based evaluation and monitoring to assess the achievements of the *vaccination* programme. Evaluation and monitoring should be carried out periodically to enable the timely application of corrective measures and to enhance the sustainability of the *vaccination* programme.

Based on the objectives and targets of the *vaccination* programme, the following outcomes should be assessed:

- 1) *vaccination* coverage stratified by species, geographical location and type of production system;
- 2) population immunity measured by testing, stratified by species, geographical location and type of production system;
- 3) frequency and severity of adverse reactions;
- 4) reduction of *incidence* or *prevalence*.

Article 4.X.10.

Exit strategy of a vaccination programme

The *vaccination* programme may provide for an exit strategy to cease *vaccination*. The cessation of *vaccination* may apply to the entire target population or to a subset of it, as defined by the *risk* of exposure and as determined by the *Veterinary Authority*.

Criteria to cease *vaccination* may include:

- 1) eradication of the *disease* in a country or zone has been achieved;
- 2) *risk analysis* demonstrates sufficient reduction of likelihood of introduction or emergence of the *disease*;
- 3) reduction of the *incidence* or *prevalence* of the *disease* to a level where alternative measures such as *stamping-out* may be sufficient to achieve *disease* control;
- 4) inability of the programme to meet the desired objectives;
- 5) adverse public reaction to the *vaccination* programme.

When the achievement of *disease* free status requires the cessation of *vaccination*, the *Veterinary Authority* should prohibit *vaccination* and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of *vaccination* may require the revision of the contingency plan and enhanced *biosecurity*, *sanitary measures* and *surveillance* for early detection of *disease*.

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate *diseases* in addition to or as alternative to stamping-out. However, depending on the *disease* and type of vaccine used, *vaccination* may mask underlying *infections*, affect *disease surveillance* and have implications for the movement of vaccinated animals and their products.

When appropriate, *vaccination* programmes should include provisions for the management of vaccinated animals such as '*vaccination to live*' or '*suppressive vaccination*' policies. *Disease-specific* chapters of the *Terrestrial Code* provide additional recommendations on the management of vaccinated animals.

Disease free countries or *zones* applying systematic or emergency *vaccination* in response to a change in the *risk* of occurrence of a *disease* should inform trading partners and the OIE, as appropriate. Unless otherwise specified in the relevant *disease-specific* chapters, *vaccination* of animals does not affect the *disease* status of the country or *zone*, and should not disrupt trade.

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